

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION**

**IN RE: NATIONAL PRESCRIPTION
OPIATE LITIGATION**

THIS DOCUMENT RELATES TO:

*The County of Summit, Ohio, et al. v.
Purdue Pharma L.P., et al.,
Case No. 18-op-45090*

*The County of Cuyahoga, Ohio, et al. v.
Purdue Pharma L.P., et al.,
Case No. 17-op-45004*

MDL No. 2804

Case No. 1:17-md-2804

Judge Dan Aaron Polster

**WALGREENS' MEMORANDUM OF LAW IN SUPPORT OF
ITS MOTION FOR SUMMARY JUDGMENT**

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Plaintiffs bring no claims against Walgreens based on its dispensing practices. The only claims against Walgreens are based on the allegedly improper distribution of prescription opioid medications back when Walgreens still distributed them—now more than five years ago. But Walgreens is a national retail chain that only ever distributed controlled substances to its own Walgreens pharmacies, Ex. 1, Decl. of Natasha Polster ¶¶ 2-3,¹ which in turn dispensed FDA-approved medications to patients with prescriptions from licensed medical professionals. Unlike wholesale distributors, Walgreens never distributed to any independent pharmacy, internet pharmacy, pain clinic, or “pill mill.” *Id.* That undisputed fact is a big reason why—despite extensive discovery and dozens of expert witnesses—Plaintiffs still have not identified any evidence to establish liability against Walgreens on any of their claims.

Combined motions by the Pharmacy Defendants and other Defendants have explained why the Court should grant summary judgment in favor of Walgreens on all claims:

- **Statute of Limitations:** Unique among all Defendant families, the statute of limitations is a complete bar on all claims against Walgreens. Walgreens’ last shipment into the Track One counties—and thus its last even arguably tortious act—occurred on April 9, 2014, beyond the reach of the longest applicable limitations period. *See* Dkt. No. 1703-1, Pharmacy SOL MSJ at 3-4. No tolling doctrines apply to save Plaintiffs’ claims, *id.* at 6-12; Dkt. No. 1691-2, Distr. & Mfr. SOL Partial MSJ at 39-47, including the continuing tort doctrine, which requires continuing **conduct** and not just continuing **injury** within the limitations period. *Sexton v. Mason*, 883 N.E.2d 1013, 1019-21 (Ohio 2008).
- **No Causation:** Plaintiffs have not identified any evidence connecting Walgreens’ alleged misconduct to Plaintiffs’ claimed harms. Aggregate proof is legally and factually insufficient. Pharmacy Causation MSJ at 3-4 (June 28, 2019). Plaintiffs have not proven and cannot prove (1) that any of Walgreens’ orders were actually suspicious; (2) that any “suspicious orders” were actually diverted; or (3) that the diversion of medications contained in suspicious orders shipped **by Walgreens** resulted in any of Plaintiffs’ claimed injuries. *Id.* at 4-12.

¹ All Exhibit references are to the Declaration of Alex J. Harris submitted with this Memorandum of Law.

- **No Conspiracy:** Even if there was a common-law conspiracy,² Walgreens was not a part of it and cannot be held responsible for the acts or omissions of any other Defendant. Dkt. No. 1716-1, Pharmacy Civil Conspiracy MSJ.
- **Preemption:** Plaintiffs' claims against Walgreens are impliedly preempted by the Controlled Substances Act (CSA) because imposing state tort liability for conduct governed by the CSA prevents DEA from striking the balance Congress intended between the prevention of diversion and the continued availability of important medications. *See* Pharmacy & Major Distr. Preemption MSJ (June 28, 2019).

To assist the Court in addressing the most important issues, this brief intentionally does not advance every ground on which summary judgment in favor of Walgreens is warranted. Instead, Walgreens incorporates by reference the arguments advanced by the other combined and Defendant-specific motions. This brief supplements the arguments in those briefs by examining a specific lack of evidence supporting Plaintiffs' claims against Walgreens in particular.

I. THERE IS NO CAUSATION AS TO WALGREENS BECAUSE THERE IS NO EVIDENCE THAT ANY OPIOIDS WERE ACTUALLY DIVERTED³

A. Plaintiffs Must Prove Actual Diversion to Establish Causation

Plaintiffs claim that when Walgreens formerly operated as a distributor, it shipped so-called "suspicious orders" (as identified after-the-fact by Plaintiffs' litigation consultants) to its stores in Cuyahoga and Summit Counties without conducting what Plaintiffs deem to be adequate due diligence (*i.e.*, "improper distribution"). The problem with this theory is that, even if Plaintiffs were correct about all this—and they are not—the alleged improper distribution by itself would *not* support the critical finding of a resulting *injury* to Plaintiffs. Any finding that Walgreens caused harm to Plaintiffs requires (at a minimum) some evidence that prescription

² Walgreens is not named in Plaintiffs' claim for RICO conspiracy.

³ To avoid unnecessary duplication, Walgreens specifically incorporates the relevant summary judgment standards, background law, and alternative arguments in the Pharmacy Defendants' and Distributors' briefs on causation. *See generally* Pharmacy Causation MSJ (June 28, 2019); Dkt. No. 1736-1, Distr. Causation MSJ.

opioid medications, shipped by Walgreens without adequate due diligence as part of a “suspicious order,” *were actually diverted outside of legitimate medical channels*.

The requirement that Plaintiffs point to evidence of actual diversion is obvious. No claim lies against Walgreens for shipping medications to its pharmacies that were simply used to fill valid prescriptions. Rather, Plaintiffs’ theory is that Walgreens’ improper distribution resulted in prescription opioid medications Walgreens shipped to its Cuyahoga and Summit County pharmacies being diverted into the illicit market. Indeed, the Court only permitted RICO claims to proceed against the major distributors (claims not asserted against Walgreens) based on Plaintiffs’ *pleading* of what the Court held were “sufficient facts” to support a “direct chain of causation,” including that “the excess opioids . . . distributed . . . *were then diverted into an illicit, black market*.” Dkt. No. 1203, Opinion & Order at 9-10 (emphasis added).⁴

Multiple DEA witnesses, including the DEA’s 30(b)(6) witness, have testified that the fact that an order is “suspicious” does not mean the medications contained in that order are necessarily destined for abuse or the illicit market. *See* Ex. 2, Prevoznik 30(b)(6) Tr. 307:18-308:17 (agreeing that an order that is “unusually large,” “unusually frequent,” or that “deviates substantially from the normal pattern” would not necessarily lead to diversion); *id.* 281:22-282:12; Ex. 3, Wright Tr. 212:24-213:2 (agreeing that “being reported as suspicious does not imply necessarily that [an order] will be diverted”); *id.* 208:14-24 (acknowledging that there were suspicious orders reported to DEA “that were not, in fact, likely to be diverted”). This is true even where the customer is inherently *more* suspect than a retail chain pharmacy like

⁴ In its Opinion and Order, the Court also recognized the need for Plaintiffs to prove that prescription opioid medications—improperly distributed and actually diverted into the illicit market—were in fact abused, resulting in injury to one or more persons in Cuyahoga or Summit Counties and causing an increase in Plaintiffs’ expenditures. *See* Dkt. No. 1203 at 10. Plaintiffs cannot prove that either, as explained in the Distributors’ and Pharmacy Defendants’ causation briefs. But Plaintiffs cannot even *reach* that step as to Walgreens because they cannot show that any purportedly “suspicious orders” shipped by Walgreens were actually diverted in the first place.

Walgreens, such as a pain clinic or internet pharmacy. Ex. 2, Prevoznik 30(b)(6) Tr. 492:4-9 (agreeing that not all pain clinics diverted controlled substances); *id.* 476:2-13 (same for internet pharmacies). Whatever volume of medication was shipped to a Walgreens store, there was no diversion and can be no liability if it simply sat on the pharmacy shelf or was dispensed to patients with valid prescriptions from licensed medical professionals.

Plaintiffs will try to argue that evidence of actual diversion is unnecessary. They will say that the total volume of prescription opioid medications being distributed, prescribed, and dispensed in Cuyahoga and Summit Counties raises an unavoidable inference of diversion. But the DEA has flatly dismissed the idea that volume alone indicates (let alone proves) actual diversion. *See* Ex. 4, *In re Masters Pharm., Inc.*, 80 Fed. Reg. 55,418, 55,426 n.15 (DEA Sept. 15, 2015) (rejecting “the allegation that the volume of dosage units distributed to the pharmacies alone establishes that the Respondent ‘knew or should have known’ that the ‘prescriptions were issued for other than a legitimate medical purpose and outside the usual course of professional practice’”). Plaintiffs’ own law enforcement officials agree. *See* Ex. 5, Leonard Tr. 427:10-428:2 (agreeing that “[v]olume alone can’t tell you that something is necessarily wrong” and stating that “[t]here’s always more factors that are looked at before an investigation is opened”); Ex. 6, Baker-Stella Tr. 412:16-413:13 (agreeing that “the number of prescriptions alone isn’t sufficient to reach a judgment about whether there’s overprescribing or not”); Ex. 7, Prince Tr. 455:14-456:11 (explaining that, “without a whole lot more information,” the fact that “Dr. X has written Y number of prescriptions for oxycodone” does not mean “Dr. X is diverting”).

Evidence of volume is all Plaintiffs have. It is not enough, and the Court should grant summary judgment in favor of Walgreens on that basis alone.

B. Plaintiffs Cannot Prove Actual Diversion as to Walgreens

Plaintiffs have not proven and cannot prove actual diversion as to Walgreens. Despite extensive discovery and dozens of expert witnesses, Plaintiffs unsurprisingly have not identified a single Walgreens store in Cuyahoga or Summit Counties that operated as a “pill mill.” This should end their claims against Walgreens. *See* Ex. 8, Status Conf. Tr. 26:18-20 (June 25, 2019) (the Court observing that, under Plaintiffs’ theory, “they would have to show that one or more of the stores of the specific pharmacy defendant was a pill mill”). Nor have Plaintiffs or their experts identified any evidence connecting any allegedly “suspicious order” shipped by Walgreens into Cuyahoga or Summit Counties to any actual diversion. Even a cursory review of the evidence on which Plaintiffs rely for their distribution claims against Walgreens demonstrates that there is no basis for a reasonable jury to find causation.

1. 2012 DEA Enforcement Action in Florida

Plaintiffs’ allegations against Walgreens are based primarily on a 2012 DEA enforcement action against a Walgreens distribution center and several pharmacies in Florida. *E.g.*, Dkt. No. 1630, Cuyahoga 3d Am. Compl. ¶¶ 618-19, 622. While the DEA’s allegations in 2012 were incomplete and misleading, for present purposes it suffices to note that they are irrelevant to distribution claims in Ohio and do not support a finding of actual diversion. None of the Florida allegations identifies a single suspicious order of prescription opioid medication that migrated from a Walgreens store in Florida to a person in Cuyahoga or Summit Counties. Likewise, none of the Florida allegations identifies a single “suspicious order” shipped by Walgreens in Florida to a Walgreens store in Ohio, much less suggests that medication contained in such an order was improperly dispensed by Walgreens pharmacists in Cuyahoga or Summit Counties.

2. Plaintiffs' Responses to Discovery Ruling No. 12

In response to a supplemental interrogatory issued by the Court in Discovery Ruling No. 12, Plaintiffs identified a total of 30 allegedly suspicious orders Walgreens shipped to 18 different Walgreens stores in Cuyahoga and Summit Counties between 2009 and 2013. *See* Exs. 9 & 10. Besides the fact that there is nothing obviously suspicious about any of the orders Plaintiffs identified, Plaintiffs were specifically directed by the Court to “explain in detail” whether and why the orders suggested to Plaintiffs that “the customer was engaged in diversion.” *See* Dkt. No. 1174, Discovery Ruling No. 12 at 14. Plaintiffs declined to do so.

3. Expert Report and Testimony of Craig McCann

McCann followed Plaintiffs' directives in applying five different methodologies to “flag” certain transactions in the ARCOS data and in Walgreens' transactional data. McCann expressly disavows any opinion on whether the orders he flagged are “suspicious,” whether any of his methodologies are consistent with the CSA or DEA regulations, or whether due diligence was actually performed. *See* Ex. 11, McCann Tr. 149:3-150:9, 206:19-207:3, 283:11-284:22. All of McCann's charts and analysis of flagged orders for Walgreens are aggregated. They show only the total number of flagged orders for *all* Walgreens shipments to *all* 59 Walgreens stores in Cuyahoga and Summit Counties *combined*. McCann presents no analysis of flagged orders at the individual store level, which is the only place where diversion could occur. In fact, McCann has no opinions about diversion. *Id.* 268:11-15, 312:17-313:23, 340:14-341:4. His reports and testimony provide no basis for a jury to conclude that any medication contained in any “suspicious order” shipped to any Walgreens pharmacy was actually diverted.

4. Expert Report and Testimony of James Rafalski

If any expert was intended to take the underlying data processed by McCann and provide some reasonable basis for a finding of actual diversion, it would have been Rafalski, Plaintiffs'

DEA expert. In fact, relying on McCann’s aggregated charts and his own review of documents, Rafalski opines that Walgreens shipped suspicious orders into Cuyahoga and Summit Counties without adequate due diligence. *See* Ex. 12, Rafalski Rpt. at 40-46.

But even Rafalski offers no opinions about actual diversion in Cuyahoga or Summit Counties, emphasizing that any determination of whether controlled substances are “likely to be diverted into illicit channels” requires a highly individualized analysis of historical transactions, trends, and other contextual factors—including the patient and physician populations served and analysis based on an “on-site customer review.” *See id.* at 36-40. At his deposition, however, Rafalski disclosed a new (and remarkable) opinion that, under his methodology, **every** single pill contained in **every** one of McCann’s “flagged” Walgreens orders—around 95% of **all** orders Walgreens ever shipped into Cuyahoga or Summit Counties from 2002 to 2014—were not only suspicious, but were **actually diverted** outside of legitimate medical channels. Ex. 13, Rafalski Tr. 474:13-475:10.

Both common sense and closer examination make clear that Rafalski has no basis whatsoever for this “opinion.” *See id.* 190:19-191:2 (admitting he cannot cite any document, research, or data for the proposition that suspicious orders are even “probably” diverted). His testimony is directly contradicted by the DEA and its witnesses. Ex. 2, Prevoznik 30(b)(6) Tr. 281:22-282:12, 307:18-308:17; Ex. 3, Wright Tr. 208:14-24, 212:24-213:2; *see also* Ex. 14, Dispensing Controlled Substances for the Treatment of Pain, 71 Fed. Reg. 52,716-01, 52,721 (Sept. 6, 2006) (policy statement by DEA explaining that “nearly every prescription” for opioids issued by a U.S. physician was “legitimate”). Rafalski’s testimony is even contradicted by Plaintiffs’ **other** experts. *See, e.g.*, Ex. 15, Lembke Tr. 224:1-15 (testifying that “pill mill

doctors . . . are not the major factor” and that “the vast majority of opioids prescribed in this country are prescribed . . . by well-intentioned doctors”); *id.* 220:24-221:7.

Beyond all of the direct contradictions, Rafalski also did not look at any of McCann’s underlying data. Ex. 13, Rafalski Tr. 468:25-469:6 (never reviewed any specific orders from McCann’s report); *id.* 489:16-19 (never looked at any order McCann flagged). He never looked at or analyzed any particular Walgreens order or individual Walgreens store. *See id.* 489:3-19 (no analysis of Walgreens orders); 487:6-19, 514:14-516:24 (no analysis of Walgreens stores). In fact, Rafalski admits he did no analysis to identify “whether any specific suspicious order caused the diversion of any specific pills.” *Id.* 469:20-470:1; *see also id.* 508:1-18 (no opinion about whether any flagged order “led to someone’s addiction, overdose or death”); *id.* 581:24-582:19 (“I don’t have any direct knowledge of what happened to any of the drugs that were distributed to each of the pharmacies. I didn’t conduct any analysis as of today that would give me that knowledge.”). In short, no reasonable jury could credit Rafalski’s unsupported “belief” about supposedly massive, but somehow undocumented, diversion from Walgreens stores.

5. Other Expert Reports and Testimony

A handful of other Plaintiffs’ experts discussed Walgreens in their reports or testimony.

None of them have disclosed any opinion or evidence of actual diversion either:

- **David Egilman’s** wild and unsupported opinions about Walgreens and the 2012 DEA enforcement action in Florida are not proper expert testimony and should be excluded in their entirety, as explained in the Defendants’ *Daubert* motion. But even if he is not excluded, Egilman’s opinions provide no basis for a finding of actual diversion in Cuyahoga or Summit Counties.⁵

⁵ Dr. Egilman opines that “DOJ recognized that Walgreens’ diversion problems stemming from its Jupiter, FL distribution center, impacted Ohio users.” Ex. 16, Egilman Rpt. at 7.107. The support for this “opinion” is the 2012 DEA enforcement action in Florida (addressed above) and general articles and press releases about drug-trafficking rings operating in Florida. None identify even a single example of prescription opioid medications shipped or dispensed by Walgreens in Florida and migrating to Cuyahoga or Summit Counties. Egilman’s primary “support,” a 2011 DOJ press release about the indictment of members of a doctor-shopping ring involving 16 West Virginia residents and 3 Ohio residents on the Ohio-West Virginia border, does not even *mention* Walgreens. *See id.*

- **Lacey R. Keller** does not discuss any orders shipped *by* Walgreens. She also expresses no opinions and provides no analysis of actual diversion. Ex. 17, Keller Tr. 386:2-6 (testifying that “whether any prescription opioids shipped to these pharmacies were diverted” was “outside of the scope of this report”).
- **Seth Whitelaw** provides no opinions about diversion or any basis to support a finding of actual diversion. Ex. 18, Whitelaw Tr. 502:14-15 (“I’m not talking about whether [Walgreens’ conduct] led to diversion or not.”); *id.* 551:8-18 (testifying that whether any shipment “was, in fact, diverted to illegitimate use” was “outside of the scope” of his report). He agrees that just because an order might be suspicious “doesn’t mean that that order will be diverted,” and testified that “[t]here could be lots of facts to take into account.” *Id.* 288:10-289:14.

No reasonable jury could conclude, based on Plaintiffs’ evidence and expert testimony, that any allegedly suspicious order shipped by Walgreens was actually diverted outside of legitimate medical channels. Because Plaintiffs are unable to prove causation, the Court should enter summary judgment in favor of Walgreens on all of Plaintiffs’ claims.

CONCLUSION

The Court should enter judgment in favor of Walgreens on all of Plaintiffs’ claims.

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Respectfully submitted,

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